UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EXPEDITE AUG 12 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration No. 1471-101 (RCB No. 4060) and Rebuttal to Label and Residue Data Deficiencies Outlined in the Tebuthiuron Registration Standard Revised Tebuthiuron Protocol to Partially Fulfill Generic Data Requirement 171-4 (Magnitude of Residue Grass Forage, Fodder, and Hay Groups) (No Accession Number)

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and

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Introduction

A review of the subject material is being expedited at the request of Edwin F. Tinsworth, Director, RD [see July 13, 1988 memorandum - E.F. Tinsworth (RD) to A.L. Barton (HED)].

In the current submission, dated February 18, 1988, Elanco Products Company has provided the Agency with arguments relating to label and residue data deficiencies outlined in the February 27, 1987 Residue Chemistry Chapter of the Tebuthiuron Registration Standard and revised protocols

dated February 15, 1988 to generate grass forage, fodder, and hay residue data necessary to fulfill the data gaps remaining in the residue chemistry portion of the Tebuthiuron Registration Standard. The revised protocols were submitted in response to Conclusion (Recommendation) 4a of the Residue Chemistry Branch (RCB) (N. Dodd) memorandum of December 10, 1987 [EPA Registration No. 1471-101 (RCB No. 2959) - Data Waiver or Amendment Request and Protocol Re: Tebuthiuron Reregistration] which stated:

> The submitted protocol for residue studies is not adequate. Issues concerning adequate geographic representation, adequate crop group member representation, aerial applications, label rate, and analytical method have not been adequately addressed in the protocol.

Summary of Deficiencies Remaining to be Resolved (see also RCB Chapter of the Tebuthiuron Registration Standard).

- Nature of the residue in animals;
- Data from FDA multiresidue protocols;
- Storage stability data;
- Data depicting tebuthiuron residues of concern in or on fresh grass and field-dried hay of Bermudagrass, bluegrass, and bromegrass or Fescue; and
- Magnitude of the residue in meat, milk, poultry, and eggs.

Conclusions:

A. Conclusions relating to the nature of the residues in animals, FDA multiresidue protocols, storage stability, and magnitude of the residue in meat, milk, poultry, and eggs as outlined in the RCB Chapter of the Tebuthiuron Registration Standard--February 27, 1987 were not addressed in the present submission. Conclusions relating to crop residue data are partially addressed by submitting the present protocol submission.

B. The deficiencies (conclusions) with regard to the present submitted residue information and revised protocols are as follows:

1. Residue data previously submitted by the registrant in MRID Nos. 20757, 41671, and 94745 and cited by the registrant in this submission as satisfying the residue data gaps identified in the Tebuthiuron Registration Standard are in RCB's opinion insufficient to support a crop group tolerance for residues of tebuthiuron in or on grass and grass hay for the following reasons:

   a. An inadequate number of residue trials were submitted that reflect the representative grass species Bermudagrass (bromegrass or fescue) and bluegrass or the dried hay of those species.

   b. The representative grass species which were tested were not adequately represented on a geographical basis.

   c. Insufficient residue trials were submitted which reflected the maximum use rates now permitted on the SPIKE 20P and 40P labels.

   d. Incomplete and inconclusive storage fortification data which were not supported by information on sample storage conditions.

2. The following amendments are recommended by RCB to the SPIKE 20P and 40P labels submitted by the registrant:

   a. Grazing and hay restrictions should be applicable to pasture uses only; these restrictions are not practical for proposed rangeland applications, therefore the SPIKE 20P label should be revised accordingly.

b. If intended by the registrant, both labels should be amended to restrict use to ground applications only for SPIKE 20P (pastures and rangelands) and SPIKE 40P (pastureland). See RCB's discussion below under Conclusion 3.c.2.

c. Restrict application on both labels to one application per year.

d. If intended by the registrant, deletion of the restriction against broadcast application of SPIKE 40P to pastureland. See RCB's discussion below under Conclusion 3.c.3.

3. The protocols submitted by the registrant for Tebuthiuron Uptake and Decline on Rangeland/ Pasture are inadequate for the following reasons:

a. The number or specific State locations of the intended "study sites" have not been identified in each of the four regions to be tested. RCB recommends study sites should be located in the following States: Northeast region (New York, Pennsylvania), North Central region (Kansas, Missouri, Oklahoma, Nebraska, North Dakota, South Dakota), Southeast region (Kentucky, Tennessee, Arkansas, Texas, and Virginia) and Western region (Colorado, Oregon, and Wyoming).

b. The representative grass species tested at each study site was not adequately representative of the region in which it was tested. In the resubmitted protocols, the representative grass species tested at each study site (i.e., (fescue/bromegrass), bluegrass, Bermudagrass) must be identified and the species must be representative for the region in which tested.

c. The formulation (SPIKE 40P) to be used in the submitted protocols, including its mode, rates of application, and nature of the sites of application are inconsistent with the directions for use on the currently approved SPIKE 20P formulation (rangeland/ pastureland) and SPIKE 40P (pastureland) labels. For example:

1) SPIKE 20P is labeled for rangeland and pastureland applications whereas SPIKE 40P is labeled for pastureland applications only. The submitted protocol proposed application of SPIKE 40P to both rangeland and pastureland.

2) The submitted protocols reflected ground application only. Unless the current labels (see RCB's Conclusion 2.b. above) are amended to restrict use to ground application only then the resubmitted protocols must be revised to reflect both ground and aerial applications.

3) The submitted protocols reflected broadcast application of the SPIKE 40P formulation. Unless the current label restriction (see RCB's Conclusion 2.d. above) against broadcast application of SPIKE 40P to pastureland is deleted by the registrant then the resubmitted protocol should reflect both broadcast and spot treatments to pastureland with both treatments at the maximum permissible label rates; if the label restriction is retained by the registrant then only spot treatments need be conducted on pastureland.

4) The proposed application rate of 2.0 lb ai/A of SPIKE 40P in the registrant's Western Region protocol is inconsistent with the currently approved SPIKE 20P label. The latter label now recommends 3.0 lb ai/A for rangeland brush control in the Western United States. The resubmitted protocol should reflect SPIKE 20P applications in the Western Region at both 4.0 and 3.0 lb ai/A.

4. The submitted analytical method utilizing gas chromatography with a flame photometric detector

is adequate to generate residue data for tebuthiuron in or on grass and grass hay including its metabolites 103(OH), 104, and 109. If the minor metabolites 104(OH), 106, 107, and 108 are determined by Toxicology Branch (TB) to be of toxicological concern, they would also have to be analyzed by this method.

Recommendations

1. RCB recommends a copy of this review be sent to the registrant.

2. RCB recommends the deficiencies cited under "Summary of Deficiencies Remaining to be Resolved" be addressed by the registrant.

3. Revised protocols should be developed, submitted by the registrant and approved by RCB before any additional residue work is done. The revised protocols must address all of the label and/or protocol deficiencies cited in this review under deficiencies (conclusions) 2.a. through 2.d. and 3.a. through 3.c.

Background

The residue chemistry deficiencies that prevent a group tolerance for the combined residues of tebuthiuron and its metabolites in or on grass and grass hay from rangeland and pastures, which were stated in detail in the Residue Chemistry Chapter of the Tebuthiuron Registration Standard dated February 27, 1987 and further cited and summarized in RCB's subsequent review (see N. Dodd's aforecited memorandum of December 10, 1987), will not be restated in the current review. A summary of those deficiencies has been given earlier in this review.

In partial response to the subject Registration Standard, Elanco Products Company submitted a letter dated October 28, 1987 with a protocol for residue data for rangeland and pastures. The protocol was titled "Uptake and Decline Protocol on Rangeland Pasture." The company also submitted a letter dated October 26, 1987 which requested extensions of time requirements for submission of plant metabolism, storage stability data, and residue data for grass and hay. Further, the company submitted another letter dated October 23, 1987, requesting that plant and animal metabolism data be waived.

In his protocol submission, the petitioner proposed analyzing fescue in California, fescue/buffel grass in Texas, fescue/Bermudagrass in Oklahoma, and bromegrass in Nebraska. One application would be made with ground equipment at the rate of 4 lb ai/A. The plots would be irrigated. Samples would be taken before treatment, immediately after treatment, at 2, 4, 6, 8, 10, and 12 weeks, and then monthly until 24 months after application. Spikes of grass and hay would be handled in the same manner as residue samples in order to check storage stability. All samples would be shipped frozen.

The petitioner's ideas which led him to formulate his protocol were summarized as follows:

1. Residue patterns from Texas into California, and Oklahoma into Nebraska are similar so that the requirements in the Registration Standard are not needed.

2. The rate to be used should be 4 lb ai/A rather than 6 lb ai/A, since the 6 lb ai/A rate is the rate used for basal treatment of perennial shrubs. (There may be 6 lb ai/A at the base of the shrub, but only 0.01 of the acre containing the treated shrub.)

3. Aerial application is not appropriate since the product is pellets and since the maximum residues would occur after ground application to a specific location.

RCB concluded in its December 10, 1987 N. Dodd review, that the submitted protocol was not adequate. Residue data would be needed from Arkansas, Kansas, Kentucky, Missouri, New York, Oklahoma, Pennsylvania, Tennessee, Texas, Virginia, Colorado, Nebraska, North Dakota, Oregon, South Dakota, and Wyoming as stated in the Residue Chemistry Chapter of the Tebuthiuron Registration Standard. Also, bluegrass must be analyzed since it is included among representative crop group members (Bermudagrass, bromegrass or fescue, and bluegrass). Residues on the representative crop group members must be determined individually. Aerial applications must be made, or directions for aerial applications must be deleted from the labels and use restricted to ground application. The application rate stated as "0.1 oz ai/2 to 4 inch of trunk diameter or at 0.13 lb ai/1000 sq ft" (5.9 lb ai/A) should be revised to reflect a rate of 4 lb ai/A if that is the intended maximum rate. The petitioner should identify the analytical method to be used to obtain the residue data (for example, Method II in Pesticide Analytical Manual, Vol. II). The metabolites which the method determines should be identified. (Note: If the minor metabolites 104(OH), 106,

107, and 108 are determined by TB to be of toxicological concern, they would also have to be analyzed.) The petitioner should state whether reported residues are corrected for control or recovery values. RCB suggested that another protocol be submitted.

RCB also concluded that the requested 19-month extension of the deadline is appropriate since samples must be collected for 2 years.

Present Considerations

The registrant, Elanco Products Company, has included the following data/information in its February 18, 1988 letter of submittal to Robert J. Taylor, PM 25, RD/EPA:

1. Addendum A: Current labels for two formulations of tebuthiuron that are currently registered for use on rangeland and/or pastures--SPIKE 20P (EPA Registration No. 1471-123) and SPIKE 40P (EPA Registration No. 1471-124).

2. Addendum B: A listing of the experiments and tebuthiuron residue data reported in MRID Nos. 20757, 41671, and 94745.

3. Addendum C: USDA publication Grazing Lands and People (A National Program Statement and Guidelines for the Cooperative Extension Service) Appendix A; pages 14 and 15.

4. Addendum D:

   a. A revised protocol, dated February 15, 1988, titled: LX 199-03 (Tebuthiuron Uptake and Decline Protocol on Rangeland/Pasture (FIFRA 171-4); applicable to the Northeast, North Central, and Southeast Regions of the United States.

   b. A revised protocol, dated February 15, 1988, titled: LX 199-03 (Tebuthiuron) Uptake and Decline Protocol on Rangeland/Pasture (FIFRA 171-4); applicable to the Western Region of the United States.

   c. A copy of the analytical procedure "Determination of Tebuthiuron and Metabolites in Grass"; A. Loh and R. Griggs, Eli Lilly and Company, Procedure 5801667 dated August 18, 1976 (MRID No. 20758).

5. Specific additional information/comments provided by the registrant in response to RCB's (N. Dodd) December 10, 1987 review or in support of the currently provided Addenda A through D, i.e.:

I. Current Labels and Use Recommendations
II. Residue Data on Various Grass Species
III. Geographic Representation of Residue Data
IV. Maximum Use Rate Residue Data
V. Spot Treatment Application Rate
VI. Need for Aerial Application
VII. Storage Conditions and Intervals

Specific data gaps stated in the Residue Chemistry Chapter of the Tebuthiuron Registration Standard and subsequently cited in RCB's (N. Dodd) December 10, 1987 memorandum re: tebuthiuron residue data in or on grass and grass hay from rangeland and pastures to support the crop group tolerance, including recommended protocol revisions delineated in the subject memorandum to fulfill these data gaps are restated below followed by the registrant's current remarks and RCB's current comments.

Tebuthiuron Registration Standard (Residue Chemistry Chapter February 27, 1987)

". . . the 1-year grazing restriction for treated rangelands is unrealistic because rangelands are not fenced and thus livestock cannot be prevented from grazing . . . ." We recommend that the 1-year grazing restriction for livestock be revoked (this would include both pasture and rangeland). The 2-year restriction on the grazing of treated pastures of dairy cattle and on the cutting of grass for hay from pasture and rangeland is practical since the cutting and harvesting of hay and the grazing of pastures are under grower control."

Registrant's Current Remarks

I. Current Labels and Use Recommendations

There are only two formulations of tebuthiuron that are currently registered for use on rangeland and/or pastures--SPIKE 20P (EPA Registration No. 1471-123) and SPIKE 40P (EPA Registration No. 1471-124). Current copies of these labels are found in Addendum A. A review of these labels will show that:

1. There is no 1-year grazing restriction of treated rangeland for livestock.

2. There is no 2-year grazing restriction of treated pastures for dairy cattle.

3. A 1-year restriction exists for cutting and harvesting of hay.

4. Livestock grazing is only allowed in areas treated with SPIKE at a rate of 4 lb ai/A or less.

RCB's Current Comments

RCB has no objections to the revised SPIKE 20P and SPIKE 40P labels which have now eliminated the 1-year grazing restriction of treated rangeland for livestock, eliminated the 2-year grazing restriction of treated pastures for dairy cattle, and imposed a 1-year restriction for cutting and harvesting of hay. The elimination of the first restriction is consistent with the recommendation made in the subject Tebuthiuron Registration Standard. Additional labeling changes to reduce the restriction on cutting grass for hay to 1 year after application and the removal of the dairy cow feeding and grazing restrictions were previously approved by RCB in its A. Smith April 13, 1983 memorandum re: a February 16, 1983 amendment to PP#2F2727: Tebuthiuron in milk.

However, RCB does recommend on the SPIKE 20P label, which permits application to both pastures and rangeland, that statements on this labeling inferring or referring to grazing restrictions applicable to rangeland applications be deleted from the label. For example, under Directions for Use, Pasture/Rangeland General Use Information: "Grazing should be deferred the following growing season to encourage grass response" should be deleted or modified to address pasture use only. In addition, on the SPIKE 20P label under Precautions Grazing and Haying the text should be revised in part as follows: "Grazing is only allowed in pasture areas treated with 20 pounds per acre or less of SPIKE 20P."

Tebuthiuron Registration Standard (Residue Chemistry Chapter February 27, 1987)

"The data are inadequate to support the crop group tolerance . . . in or on grass and grass hay from rangeland or pastures because all the data were submitted for unidentified 'grass' or 'forage' samples and none were submitted for the representative crop groups members (Bermudagrass, bromegrass or fescue, and bluegrass). Data on representative crop group members are required for systemic pesticides."

Registrant's Current Remarks

II. Residue Data on Various Grass Species

The RCB review indicated that "all data were submitted for unidentified grass or forage grass samples and none were submitted for the representative crop group members."

The Residue Chemistry Chapter of the Tebuthiuron Registration Standard (pages 29 through 32) indicates that data contained in MRID Nos. 20757, 41671, and 94745 were acceptable from the standpoint that residues of both tebuthiuron and specified metabolites were reported. Addendum B contains a listing of the experiments and residue data reported in the above MRIDs. The summarized data have been sorted by experiment number and by rate. In reviewing the original plant sample submission sheets and/or experimental write-ups, specific grass species data were able to be ascertained for several experiments and are so indicated. As you will now note, species information has been identified in 21 of the 34 experiments contained within MRID Nos. 20757, 41671, and 94745. The four representative crop group members are among the species tested.

RCB's Current Comments

As requested by the Tebuthiuron Registration Standard, the registrant has provided in Addendum B species information for most of the residue experiments conducted in conjunction with MRID Nos. 20757, 41671, and 94745. However, the additional information provided by the registrant now indicates to RCB that very few of the total experiments/ trials were conducted with representative crop group members. For example: in MRID No. 41671 only 1 out of 6 experiments for which grass species were identified [Bermudagrass (Texas)] reflected a representative crop group member. In MRID No. 20757 only 2 out of 7 experiments in which grass species were identified [Bermudagrass (Texas) and tall fescue (Oklahoma)] and in MRID No. 94745 only 3 out of 11 experiments in which grass species were identified [tall fescue (Indiana), Kentucky bluegrass (Colorado) and Downy bromegrass (Washington)] reflected a representative crop group member. Overall, the submitted experiments/trials in which the representative grass species were identified, Bermudagrass (2), tall fescue (2), Kentucky bluegrass (1) and bromegrass (1) are extremely limited in number, do not reflect residues in or on dried hay of Bermudagrass, bluegrass, and bromegrass or fescue and therefore are insufficient to support a crop group tolerance for residues of tebuthiuron in or on grass and grass hay from rangeland and pastures.

Tebuthiuron Registration Standard (Residue Chemistry Chapter February 27, 1987)

"The data are inadequate to support the crop group tolerance . . . in or on grass and grass hay from rangeland or pastures because . . . . (i) geographic representation was inadequate for both pasture and rangeland grasses."

Registrant's Current Remarks

III. Geographic Representation of Residue Data

The RCB review stated that "geographic representation was inadequate for both pasture and rangeland grasses" and that additional tests must be conducted in numerous States based on domestic and wild hay production. Domestic and wild hay production, however, do not accurately reflect pasture and rangeland because areas routinely cut for hay do not have woody plant problems that would warrant the use of tebuthiuron. Grazed areas, however, are typically invaded by woody plants. Addendum C contains a regionalized breakout of the State grazing land acreages in the United States which accurately reflects pasture and rangeland.

The Agency has requested that tests be conducted in Arkansas, Kansas, Kentucky, Missouri, New York, Oklahoma, Pennsylvania, Tennessee, Texas, Virginia, Colorado, Nebraska, North Dakota, Oregon, South Dakota, and Wyoming. Collectively, the regionalized breakout in Addendum C shows these States represent approximately 47 percent of the total grazing land (excluding Alaska) in the United States. Addendum B contains residue information from New York, Texas, Indiana, Oklahoma, Georgia, Arkansas, Arizona, Missouri, Mississippi, Colorado, Oregon, Idaho, Wyoming, and Washington which represent approximately 48 percent of the total grazing land. Thus, the geographic representation of previously submitted residue data appears to be adequate for it is equivalent to that proposed by the Agency.

RCB's Current Comments

Just because the States (16) recommended by the Agency for tebuthiuron residue testing collectively represent ca. 47 percent of the total U.S. grazing land acreage whereas the States (14) cited by the registrant in Addendum B in which previous residue trials were conducted collectively represent ca. 48 percent of the total U.S. grazing land acreage does not in itself ensure equivalency of adequate geographic representation for the previously submitted residue data.

For example, only 8 of the 14 States in which the registrant conducted residue trials (New York, Texas, Oklahoma, Arkansas, Missouri, Colorado, and Wyoming) have been recommended by the Agency for residue testing in the Registration Standard, and of these States only 3 (Texas, Oklahoma, and Colorado) reflected residue trials with the Agency's recommended crop group members (Bermudagrass, bromegrass or fescue, and bluegrass). In addition, no residue data was provided by the registrant from the eight additional States (Kansas, Kentucky, Pennsylvania, Tennessee, Virginia, Nebraska, North Dakota, and South Dakota) recommended by the Agency in the Registration Standard which represent the North Central, Northeast, and Southeast regions of the U.S. Therefore, overall only 3 of the 16 States recommended by the Agency (Texas, Oklahoma, and Colorado) representing only two regions, the Southeast and Western, and collectively representing only 18 percent of the total U.S. grazing land acreage reflected residue data in the representative grass species recommended by the Agency in the Tebuthiuron Registration Standard.

Tebuthiuron Registration Standard (Residue Chemistry Chapter February 27, 1987)

"The data are inadequate to support the crop group tolerance . . . in or on grass and grass hay from rangeland or pastures because . . . (iii) the number of tests reflecting the maximum use rate of 4 lb ai/A was meager."

Registrant's Current Remarks

IV. Maximum Use Rate Residue Data

The RCB review indicates "the number of tests reflecting the maximum use rate of 4 lb/A (a.i.) was meager."

In Addendum B, 210 analytical values are represented of which 29 percent are from 4 lb/A or higher, 40 percent from 2 to 4 lb/A and 32 percent from rates under 2 lb/A.

Four lb/A residue data were obtained from experiments in New York, Texas, Oklahoma, Georgia, and Arkansas. These States represent approximately 19 percent of the total grazing land. However, when one considers that the normal maximum broadcast use rate of SPIKE in the Western United States is 2 lb/A, then maximum use rate residue data are also available from Arizona, Colorado, Oregon, and Idaho. These States also account for approximately 19 percent of the total grazing land.

RCB's Current Comments

Although 4.00 lb ai/A (1X) residue data were obtained by the registrant from experiments conducted in New York, Texas, Indiana, Oklahoma, Georgia, and Arkansas, which collectively represented 19 percent of the total U.S. grazing land, only 3 of these experiments/trials reflected residue data obtained from 2 of the 3 Agency recommended crop group members [tall fescue (Indiana/Oklahoma) and Bermudagrass (Texas)]. No residue data reflecting the maximum 4.0 lb ai/A use rate on rangeland and pastures was submitted by the registrant for the third representative grass species, bluegrass.

RCB notes that the original residue data submitted by the registrant in addendum B (MRID Nos. 20757, 41671, and 94745) at 4.0 lb ai/A for areas receiving more than 20 inches of annual precipitation and 2.0 lb ai/A for areas receiving less than 20 inches of annual precipitation both reflected the maximum use rate then recommended on the approved GRASLAN 20P label (EPA Registration No. 1471-109) and GRASLAN 40P label (EPA Registration No. 1471-119). The use rates recommended on these labels were for the control of brush on rangeland only in Arizona, Arkansas, Colorado, Idaho, Kansas, Missouri, Montana, New Mexico, Nevada, Oklahoma, Oregon, Texas, Utah, Washington, and Wyoming. According to the currently submitted SPIKE 20P Label approved by the Agency on 9/10/87, the maximum recommended application for rangland brush control in the Western United States is now 15 lb SPIKE 20P/A (3.0 lb ai/A); for pasture, rangeland, and on additional sites in all regions of the United States, SPIKE 20P may now be applied at rates up to 20 lb/A (4.0 lb ai/A). According to the currently submitted SPIKE 40P label, also approved by the Agency on September 10, 1987, the maximum recommended broadcast application rate for woody plant species control in noncropland areas (other than pastureland) is 15 lb SPIKE 40P/A (6.0 lb ai/A); for individual plant treatments in pastureland, 1/4 oz per 2 to 4 inches of stem diameter or 1/4 oz per 45 square feet (approximately 6 lb ai/A).

Therefore, the statement by the registrant that the normal maximum broadcast use rate of SPIKE in the Western United States is 2 lb ai/A is now incorrect since this use rate is inconsistent with currently approved labels for SPIKE 20P and 40P.

RCB concludes that the previously submitted tebuthiuron residue data on grass and grass hay from rangeland and pastures are inadequate to support the maximum use rates now permitted on the current SPIKE 20P and 40P labels.

RCB's Original Remarks (N. Dodd December 10, 1987 Memorandum)

"The application rate stated as '0.1 oz ai/2 to 4 inch of trunk diameter or at 0.13 lb ai/1000 sq ft' (5.9 lb ai/A) should be revised to reflect a rate of 4 lb ai/A if that is the intended maximum rate."

Registrant's Current Remarks

V. Spot Treatment Application Rate

The current SPIKE 20P and SPIKE 40P labels provide for use directions as follows:

1. 20P--1/2 oz per 2 to 4 inches of stem diameter or 1/2 oz per 45 square feet.

2. 40P--1/4 oz per 2 to 4 inches of stem diameter or 1/4 oz per 45 square feet.

On a broadcast basis, 1/4 oz of SPIKE 40P per 45 sq ft is equivalent to approximately 6 lb ai/A. However, spot treatment of brush is made when densities are a maximum of 40 to 50 per acre. Thus, 50 brush plants, treated on an individual basis, result in total chemical applied per acre of considerably less than the maximum broadcast rate of 4 lb/A. Thus, the current spot treatment application rate around the individual brush plants should not have to be reduced.

RCB's Current Comments

RCB has no objection to the restated use rates for spot treatment applications on the current SPIKE 20P and 40P labels. According to the registrant, these rates correspond to an effective broadcast rate of ca. 4 lb ai/A although the calculated rate can be as high as 6 lb ai/A when normalized on an acre basis.

RCB recommends that this use pattern (spot treatments), at the maximum permissible application rate be employed in future residue trials with SPIKE 40P applied to pasture-land containing representative grass species (Bermudagrass, bromegrass or fescue, and bluegrass).

RCB's Original Remarks (N. Dodd, December 10, 1987 Memorandum)

"Aerial applications must be made, or directions for aerial applications must be deleted from the labels and use restricted to ground applications."

Registrant's Current Remarks

VI. Need for Aerial Application

RCB indicates "aerial applications must be made, or directions for aerial applications must be deleted from the labels and use restricted to ground application."

Again, the tebuthiuron formulations used on rangeland and pastures are a clay pellet approximately 3 millimeters in diameter and 6 millimeters in length possessing a bulk density of approximately 55 lb per cu ft. Since chemical concentration is not a factor in aerial application of these pellets, the need for aerial application in conducting any magnitude of residue study is not justified.

RCB's Current Comments

RCB disagrees with the registrant's position that the need for aerial application in conducting any magnitude of the residue study is not justified.

The Residue Chemistry Chapter of the Tebuthiuron Registration Standard states "The 20% and 40% P/T are registered for a single broadcast application to rangeland and forage grasses by ground or air equipment (aerially applied in areas with high density brush infestations)." The Standard further notes in part that the registrant's 1979 tebuthiuron residue data on grass and hay (MRID No. 94745), which was also included in the current submission under Addendum B, from Arizona, Colorado, Idaho, Oregon, Missouri, Mississippi, and New York reflected a single application of the 20% P/T formulation by both ground and air equipment.

The current SPIKE 20P label does not specifically address or prohibit aerial applications but merely states that "Spike 20P must be applied using equipment properly calibrated to provide a uniform distribution of pellets." The current SPIKE 40P label states in part: "SPIKE 40P may be applied using properly calibrated ground equipment. On utility rights-of-way, SPIKE 40P may be applied using a helicopter equipped with application equipment such as Simplex Models 1610 and 1620. Do not broadcast SPIKE 40P on pastureland."

In the protocols submitted by the registrant and discussed below, one broadcast ground application of SPIKE 40P is recommended. If that is the intent of the registrant, then both labels should be amended to restrict use to ground

applications only for SPIKE 20P (pastures and rangeland) and SPIKE 40P (pastureland), and the broadcast restriction for 40P on pastureland removed and, in addition, the following restriction should be added to both labels "Apply SPIKE 20P or 40P only once per year." The latter use restriction appeared on the previously approved GRASLAN 20P and GRASLAN 40P labels.

If these labels are not amended to restrict use to ground applications only on pastures and rangeland (SPIKE 20P) or to pastureland (SPIKE 40P), then future residue data generated for tebuthiuron in or on grass and grass hay from rangeland or pastures must reflect both ground and aerial applications of these formulations.

Tebuthiuron Registration Standard (Residue Chemistry Chapter February 27, 1988)

"The data are inadequate to support the crop group tolerance . . . in or on grass and grass hay from rangeland or pastures because . . . (ii) information on storage conditions and intervals was lacking."

Registrant's Current Remarks

VII. Storage Conditions and Intervals

Data are available, as indicated in Addendum B, on a number of the residue samples contained in MRID Nos. 20757, 41671, and 94765. Fortified samples were stored with the experimental samples; hence, results reflect the effect of storage conditions.

RCB's Current Comments

Since information on storage conditions for samples cited by the registrant in Addendum B were not provided the information which was provided for storage intervals and recovery of parent compound from fortified and stored controls for the representative grass species fescue, Bermudagrass, and bromegrass were incomplete and inconclusive. For example: fescue stored 114 to 219 days, percent recovery, 92 to 225 percent; Bermudagrass stored 128 to 199 days, percent recovery, 116 to 125 percent; bromegrass stored 405 days, percent recovery, 150 percent.

RCB concludes that sample integrity and storage conditions of previously submitted residue samples in MRID Nos. 20757, 41671, and 94745 were not adequately demonstrated.

Addendum D (Revised Protocols)

Registrant's Original Protocol (N. Dodd December 10, 1987 Memorandum)

The original protocol is essentially identical to the protocols currently submitted with the following exceptions:

Protocol Numbers and Study Locations

1714-87-99-03-18A-01 (California) - Fescue
1714-87-99-03-18A-02 (Texas) - Fescue/Buffel Grass
1714-87-99-03-18A-03 (Oklahoma) - Fescue/Bermuda
1714-87-99-03-18A-03 (Nebraska) - Brome

RCB's Original Remarks (N. Dodd December 10, 1987 Memorandum)

The submitted protocol is not adequate. Residue data will be needed from Arkansas, Kansas, Kentucky, Missouri, New York, Oklahoma, Pennsylvania, Tennessee, Texas, Virginia, Colorado, Nebraska, North Dakota, Oregon, South Dakota, and Wyoming as stated in the Residue Chemistry Chapter of the Tebuthiuron Registration Standard. Also, bluegrass must be analyzed since it is included among representative crop group members (Bermudagrass, bromegrass or fescue, and bluegrass). Residues on the representative crop group members must be determined individually. Aerial applications must be made, or directions for aerial applications must be deleted from the labels and use restricted to ground application. The application rate stated as "0.1 oz ai/2 to 4 inch of trunk diameter or at 0.13 lb ai/1000 sq ft" (5.9 lb ai/A) should be revised to reflect a rate of 4 lb ai/A if that is the intended maximum rate. The petitioner should identify the analytical method to be used to obtain the residue data (for example, Method II in Pesticide Analytical Manual, Vol. II). The metabolites which the method determines should be identified. (Note: If the minor metabolites 104(OH), 106, 107, and 108 are determined by TB to be of toxicological concern, they would also have to be analyzed.) The petitioner should state whether reported residues are corrected for control or recovery values. RCB suggests that another protocol be submitted.

Registrant's Current Remarks

Based on the aforementioned (Items I through VII discussed in conjunction with Addenda A through C), a revised protocol (Addendum D) is again submitted to address the issue of the magnitude of residue of tebuthiuron in grass forage, fodder, and hay. Included as a portion of this protocol is

the analytical procedure used to define the residue. The procedure to be used does not analyze for the minor metabolites 104(OH), 106, 107, and 108; however, since each of these metabolites is expected to consist of only 1 to 2.4 percent of the terminal residue, they are assumed to be now, as in the past, of no toxicological concern.

LX199-03 (TEBUTHIURON) UPTAKE AND DECLINE
PROTOCOL ON RANGELAND/PASTURE
(FIFRA 171-4)

Chemical: LX199-03 Formulation: 40 Pellet

Protocol Issuance Date: 02/15/88 (Draft)

Crop and Variety: Rangeland/Pasture

Sponsor's Name and Location: Client #99

Study Initiation: To Be Determined Study Completion: To Be Determined

Protocol Numbers and Study Locations:

1714-88-99-03-18A-01 (Northeast Region) - Fescue

1714-88-99-03-18A-02 (North Central Region) - Bluegrass

1714-88-99-03-18A-03 (Southeast Region) - Bermudagrass

Objective

The objective of this study is to determine the uptake and decline of LX199-03 on rangeland and pasture.

Use Pattern

One ground application of LX199-03 will be made to the test area using a pellet applicator, cyclone spreader, or other spreading device on the first day of April 1988, to study sites located in the Northeast, North Central, and Southeast regions of the United States. The application rate will be 4 lb ai/A (4.48 kg/ha). Following the application, irrigation will be utilized in order to maintain uniform plant development during the growing season. One 50 g sample of the test material will be taken prior to application for analysis.

LX199-03 (TEBUTHIURON) UPTAKE AND DECLINE
PROTOCOL ON RANGELAND/PASTURE
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Chemical: LX199-03 Formulation: 40 Pellet

Protocol Issuance Date: 02/15/88 (Draft)

Crop and Variety: Rangeland/Pasture

Sponsor's Name and Location: Client #99

Study Initiation: To Be Determined Study Completion: To Be Determined

Protocol Numbers and Study Locations:

1714-88-99-03-18A-04 (Western Region) - Existing perennial

Objective

The objective of this study is to determine the uptake and decline of LX199-03 on rangeland and pasture.

Use Pattern

Two ground applications of LX199-03 will be made to the test areas using a pellet applicator, cyclone spreader, or other spreading device on the first day of April 1988, to a study site located in the Western region of the United States. The application rate will be 4 lb ai/A (4.48 kg/ha) and 2 lb ai/A (2.24 kg/ha). Each rate will be represented with four replicates. Following the application, irrigation will be utilized in order to maintain uniform plant development during the growing season. One 50 g sample of the test material will be taken prior to application for analysis.

Reviewer's Note: The remainder of both of these protocols re: Replication, Plot Design, Sampling, Plot Maintenance, Shipping, Weather Data, and Quality Control and Quality Assurance are not reproduced here since the information is essentially identical to that protocol information which was favorably reviewed by RCB in its N. Dodd December 10, 1987 memorandum.

Registrant's Current Remarks (cont'd)

Analytical Procedure

Tebuthiuron in grass samples from the magnitude of residue samples will be measured using Procedure 5801667 "Determination of Tebuthiuron and Metabolites in Grass," A. Loh and R. Griggs (1976) (attached) (MRID No. 20758). Tebuthiuron and metabolites are extracted from grass by refluxing with a mixture of methanol and hydrochloric acid. The extract is partitioned into ethyl acetate and purified by alumina column chromatography. Tebuthiuron and metabolites are measured by gas chromatography with flame photometric detection (FPD).

Procedure 58120667 measures tebuthiuron, 103(OH) and 104 + 109. The method may also measure 104(OH) though no validation work has been done on this metabolite. The method does not measure 106, 107, or 108.

The method also specifies that samples of control grass fortified with a mixture of 103 and metabolites be analyzed with each sample set to determine the method efficiency. All sample results are corrected for the method efficiency obtained. Sample results are not corrected for background observed in control samples.

The method specifies that the tebuthiuron be measured by gas chromatography with FPD with the option of measuring 103(OH) using GCMS. The analytical laboratory will have the option of utilizing GCMS, nitrogen, or other detection techniques if validation data are generated before sample analysis.

RCB's Current Comments (Northeast, North Central, Southeast Region Protocol)

The currently submitted protocol is not adequate for the following reasons. The registrant has not indicated the number or specific locations of the intended "study sites" located in the Northeast, North Central, and Southeast regions of the United States. Study sites should be located in the following States: Northeast region (New York, Pennsylvania), North Central region (Kansas, Missouri, Oklahoma, Nebraska, North Dakota and South Dakota), and the Southeast region (Kentucky, Tennessee, Arkansas, Texas, and Virginia). The representative grass species tested at each study site (i.e., fescue/bromegrass, bluegrass, Bermudagrass) must be identified for each test and the species must be representative for the region in which it was tested. In addition, the formulations to be used in the rangeland/pasture-land protocols including their mode and rates of application and the nature of the sites to be treated must be consistent

with the currently approved labels for SPIKE 20P and SPIKE 40P. In many respects, the currently submitted protocol is inconsistent with the directions for use on these labels. For example, the 40 Pellet formulation is approved only for pastureland use, the 20 Pellet formulation is approved for use on both pastureland and rangeland although the current pastureland and rangeland. In addition, the currently approved SPIKE 40P label prohibits broadcast applications on pastureland although the current protocol specifies this mode of application. The currently submitted protocol reflects ground application only whereas the currently approved SPIKE 20P and 40P labels do not specifically restrict use to ground application only. Unless the current labels are amended to restrict use to ground application only then the resubmitted protocols must reflect both ground and aerial applications of both formulations. If the current label restriction against broadcast application of SPIKE 40P on pastureland is removed by the registrant, then the resubmitted protocols should also reflect both broadcast and spot treatment applications with both treatments at the maximum permissible label rates. If the label restriction is retained by the registrant then only spot treatments need be conducted on pastureland.

The aforementioned label and/or protocol revisions must be made by the registrant to assure label/protocol compatibility in regard to the new protocols resubmitted for RCB's evaluation for the Northeast, North Central, and Southeast regions.

RCB's Current Comments: (Western Region Protocol)

The currently submitted protocol is not adequate for the following reasons. The registrant has not indicated the number or specific locations of the intended "study sites" located in the Western region of the United States. Study sites should be located in Colorado, Oregon, and Wyoming. The registrant's designation of "existing perennial" grasses to be tested is not specific enough. The representative grass species tested at each study site (i.e., fescue/bromegrass, bluegrass, Bermudagrass, as appropriate) must be identified for each test and the species must be representative for the region in which it was tested. In addition to all of the labeling/protocol inconsistencies noted by RCB above for the Northeast, North Central, and Southeast region protocol, Western region protocol. To be consistent with the current SPIKE 20P label which now recommends 15 lb SPIKE 20P/A (3.0 lb ai/A) for rangeland brush control in the Western United States the resubmitted protocol for the Western region should employ application of the SPIKE 20P formulation at 4.0 lb ai/A and 3.0 lb ai/A, not the 2.0 lb ai/A currently proposed in the subject protocol. The 2.0 lb ai/A maximum use rate on the

old GRASLAN 20P label was applicable to areas (most of the Western U.S.) receiving less than 20 inches of annual precipitation.

The aforementioned label and/or protocol revisions must be made by the registrant to assure label/protocol compatibility in regard to the new protocol resubmitted for RCB's evaluation for the Western region.

RCB's Current Comments (Analytical Procedure)

The registrant has complied with RCB's original request (N. Dodd December 10, 1987 memorandum) to identify the analytical method to be used to obtain the residue data, identify the metabolites which the method determines and stated whether reported residues are corrected for control or recovery values. The submitted method does not measure the minor metabolites 106, 107, or 108, measures 104(OH) but the method has not been validated for the latter. RCB reiterates its previous recommendation (N. Dodd, December 10, 1987 memorandum) that if the minor metabolites 104(OH), 106, 107, and 108 are determined by TB to be of toxicological concern, they would also have to be analyzed by the analytical method used to obtain the residue data.

cc: Reviewer(M.Kovacs),TOX,Registration Standard(Tebuthiuron), RF,SF(Tebuthiuron),Circulation(7),E. Eldredge(ISB/PMSD)
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